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October 11, 1999 '99 OCT 12 09:42

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Re: Docket # (99D2635)

Dear Sirs:

The FDA Guidance for Industry re: ANDA: Blend Uniformity Analysis is a draft document which should not be finalized. The document is written to define the in-process testing requirements for adequacy of mixing to ensure uniformity and homogeneity established under 21 CFR 211.110 (a)(3). Clearly, the interpretation and the enforcement of this Regulation have been the responsibility of the Field FDA workforce, under direction of the FDA CDER Compliance office, and not CDER reviewers.

Over the years there has been a gradual increase in the amount of routine manufacturing and control information requested by Center for Drugs reviewers. The request and submission of this information presents a duplication of work for FDA since the accountability of a company to comply with CGMP Regulations has always been a local Field FDA responsibility. It represents a classic case for redundancy and non-efficient utilization of Government resources. Obviously, it also increases the time and cost of filing and goes beyond the responsibilities of CDER reviewers.

While the technical comments of the Draft Guidance for Industry Blend Uniformity may be debated, the concept of submitting specific in-process procedures in a filing is neither warranted nor prescribed by the NDA Regulations.

With increases in technology, and with many different manufacturing procedures, there can be many different means to assure uniformity and homogeneity in manufacturing processes. By publishing a Guidance document, CDER is restricting the flexibility that is inherent in the CGMP Regulations. Again, the oversight for CGMP Regulation enforcement does not reside with CDER reviewers.

In conclusion, the publication of this document in its current format will increase costs, with no apparent gain, and could restrict technology and the flexibility built into the CGMP Regulations.

Regards,


Hank Avallone

99D-2635

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